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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,802	03/20/2001	Kazuya Kawasaki	JG-TT-5053 / 500568.20026	1201
26418	7590	03/29/2005	EXAMINER	
REED SMITH, LLP			ALEXANDER, LYLE	
ATTN: PATENT RECORDS DEPARTMENT			ART UNIT	
599 LEXINGTON AVENUE, 29TH FLOOR			PAPER NUMBER	
NEW YORK, NY 10022-7650			1743	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,802

Applicant(s)

KAWASAKI ET AL.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is not clear what a "punching sheet" intends.

Claims 11-12 are vague and indefinite how these structures can have the claimed aperture diameter because these shapes are not round (e.g. diameter is best understood as only applying to round shapes).

Claim 14 is not clear what structure is intended by "a water impermeably body which defines compartments... ". In the absence of better defining the frame/body defining a compartment, the Office has read this as a single compartment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-8, 10 and 13-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Amano et al. (USP 5,508,173).

Amano et al. teach a multilayer test strip comprising a water impermeable and light transmissive hydrophilic support, a reagent layer and a porous spreading layer. Column 3 lines 45+ through column 4 teach the support may be made of PET which is identical to the example in the original that teaches this layer to be made of the same

Art Unit: 1743

polymer. The reagent layer is taught in column 4 as being a hydrophilic polymer such as gelatin with binders of PVA, PET or cellulose acetate that have an approximate thickness between 3 and 50 microns in the dry state which has been read on the claimed polymer. The spreading layer is taught as having a void volume of 3 to 15 micro liters per square centimeter and has been read on the claimed mesh layer having an aperture diameter of between 0.05-7.5mm. Column 6 teaches examples of the spreading layer. The structure supporting the layers has been read on the claimed "... water impermeable frame body with defines a compartment ...". In light of the 35 USC 112 issues above, it is difficult for the Office to know what is intended by the claimed "punching sheet" and this has been interpreted as a sheet with circular holes which is indistinguishable from Amano et al.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amano et al. (USP 5,508,173).

Sée Amano et al. *supra*.

Amano et al. is silent to the mesh in the shape of tetragon or hexagon.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The shape of a mesh is a result effective variable having the expected result of permitting the transfer of material. The shape

Art Unit: 1743

may be dependent upon the material used for the mesh and would have been expected to permit transfer of the material.

It would have been within the skill of the art to modify Amano et al. and use a material having meshes in the shape of a tetragon or a hexagon as optimization of a result effective to gain the well known and expected advantages of permitting fluid transfer.

The court decided In re Dailey (149 USPQ 47) " the configuration of the container is a mere matter of choice not significant" to define over art that has the same elements" but a different shape. Hexagonal and tetragon shapes have the advantages of minimizing the void volume between adjacent plates by the fact they fit together well. It would have been within the skill of the art to modify Amano et al. and use a tetragon or hexagon shape for the plate to minimize the void volume between interconnecting plates because the configuration of the plate is " a mere matter of choice".

Response to Arguments

Applicant's arguments with respect to claims 4-8 and 9-18 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

Claims 14-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/858,392. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an analytical test

Art Unit: 1743

device having an impermeable bottom and wells on top of the bottom containing the appropriate reagents to accomplish the desired analysis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743


